§ 620.46 General requirements.

(a) *Dose.* These standards are based on (1) vaccine intended for intradermal injection in a single human immunizing dose of 0.1 milliliter and (2) vaccine intended for percutaneous injection in a single skin application through which inoculation is made by a multiple puncture device.

(b) *Date of manufacture.* The date of manufacture is the date of initiation of the last valid determination for CFU after freeze-drying.

§ 620.47 Labeling.

In addition to conforming to the applicable requirements of §§ 610.60, 610.61, and 610.62 of this chapter, the package label must bear the following information:

(a) Specification of the route of administration.

(b) A statement that the vaccine contains live bacteria and should be protected against exposure to light.

(c) A statement that the vaccine must be administered within 8 hours after reconstitution, and that reconstituted vaccine not used within 8 hours must be discarded.

§ 620.48 Samples; protocols; official release.

(a) For each lot of vaccine, the following materials must be submitted to the Director, Center for Biologics Evaluation and Research, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892.

(1) Samples and diluent that will provide at least 20 milliliters when the samples are reconstituted as recommended in the package insert by the manufacturer of the vaccine.

(2) A protocol that consists of a complete summary of the manufacture of each lot, including all results of each test required by all applicable regulations. If the protocol is not included in the shipment of the samples, it must be sent promptly to the Director, Center for Biologics Evaluation and Research, Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892.

(b) The BCG Vaccine must not be issued by the manufacturer until written notification of official release is received from the Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

[44 FR 14545, Mar. 13, 1979, as amended at 49 FR 23834, June 8, 1984; 51 FR 15610, Apr. 25, 1986; 55 FR 11013, Mar. 26, 1990]

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

Subpart A—Poliovirus Vaccine Inactivated

Subpart B—Poliovirus Vaccine Live Oral Trivalent

Subpart C—[Reserved]

Subpart D—Measles Virus Vaccine Live

Subpart E—[Reserved]

Subpart F—Mumps Virus Vaccine Live

Subpart G—Rubella Virus Vaccine Live